K090709

SECTION 5: 510(k) Summary

JUL - 7 2009

Submitter

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Date Prepared

March, 2009

Device Information

Trade Name: Cortex Dental Implant system
Product Code: DZE, NHA
Regulation Name: Endosseous dental implant
Regulation Number: 872.3640
Device Class: Class II
Review Panel: Dental

Devices to which substantial equivalence is claimed:

510(k) No.	Trade or propriety name	Manufacturer
K040807	MIS Dental Implant System (specifically the Seven implant series)	MIS - Implant Technologies Ltd.
K080162	Uno - One Piece Screw-Type Dental Implant	MIS - Implant Technologies Ltd.
K030007	Legacy System Dental Implants	Implant Direct LLC

Device Description

The **Cortex Dental Implant System** includes an integral array of devices comprising mainly of dental implants, abutments, additional prosthetic and surgical components, post surgical components, and surgical instruments.

Intended Use

The **Cortex Dental Implant System** is indicated for use in surgical (single-stage or two-stage procedures) and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications.

Performance

Mechanical strength testing of the implant system was performed according to FDA "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments"

The specimen tested represents the most vulnerable system configuration (worst case). Test results show that the implant/abutment combination is highly resistant

The Acid Treatment Process was designed in compliance with the guidelines of ASTM B 600-91.

SEM-EDS results demonstrated how the process saves the morphology of the surface. Process validation also verified that that implant surface is indeed cleaned from all alumina residuals and washing detergents used during the machining and alumina blasting.

Conclusion

The Cortex Dental Implant System, subject of this submission, constitutes a **safe, reliable and effective** medical device, meeting all the declared requirements of its intended use. Device presents **no adverse health effects or safety risks to patients** when used as intended.

The Cortex Dental Implant System has the **same intended use and fundamental scientific technology** as its predicate devices – the MIS Dental Implant System (specifically the Seven implant series - K040807) and Uno - One Piece Screw-Type Dental Implant (K080162) by MIS - Implant Technologies Ltd.; and the Legacy System Dental Implants by Implant Direct LLC (K030007).

We therefore believe that the Cortex Dental Implant System and its predicate devices are **substantially equivalent**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cortex Dental Implants Industries, Limited
Mr. Benny Arazy
Chief Executive Officer and President
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NOV 28 2011

Re: K090709
Trade/Device Name: Cortex Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated (Date on orig SE ltr): July 7, 2009
Received (Date on orig SE ltr): July 1, 2009

Dear Mr. Arazy:

This letter corrects our substantially equivalent letter of July 7, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION 4: Indications for Use

510(k) Number: K09 0709

Device Name:

Cortex Dental Implant System

Intended Use:

The Cortex Dental Implant System is indicated for use in surgical (single-stage or two-stage procedures) and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The System is intended to be used in either single tooth or multiple teeth applications.

Prescription Use ___√___ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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[signature] for [initials]

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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